UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: BIOPURE SECURITIES LITIGATION	**Civil Action No. 03-12628-NG** **JURY TRIAL DEMANDED**

CONSOLIDATED AMENDED COMPLAINT

Lead Plaintiff, Ronald Erickson, and Plaintiffs, Stuart Gottlieb, John G. Esposito, Jr., and Emily A. Bittman, through their attorneys, allege the following upon information and belief, except as to the allegations which pertain to the Plaintiffs and their counsel, which are alleged upon personal knowledge. Plaintiffs' information and belief are based, *inter alia*, on the investigation made by and through his attorneys.

INTRODUCTION

1. This is a federal securities class action which is brought by the Plaintiffs against the Defendants, Biopure Corporation ("Biopure" or the "Company") and Biopure's past or present officers and directors, Thomas A. Moore, Carl W. Rausch, Ronald Richards, and Howard P. Richman, on behalf of a class (the "Class") consisting of all persons or entities who acquired the common stock of Biopure during the period March 17, 2003 through December 24, 2003, inclusive (the "Class Period"). Plaintiffs seek to recover damages caused to the Class by Defendants' violations of Sec. 10(b) of the Securities

Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder. This action is also brought under Section 20A of the Exchange Act on behalf of all persons who purchased Biopure common stock contemporaneously with the sales of Biopure's stock by the Defendants Biopure and Rausch (the "Sub-Class") during the Class Period.

2. Biopure develops, manufacturers and markets oxygen therapeutics, for both human and veterinary use, designed to serve as an alternative to red blood cell transfusions and for use in the treatment of other critical care conditions. The Company has developed and manufactures two products: Hemopure – 250 (bovine), or HBOC-201 – for human use, and Oxyglobin – hemoglobin glutamer – 200 (bovine), or HBOC-301 – for veterinary use. Oxyglobin is approved for use in the United States for administration to dogs. Hemopure is approved in South Africa for use in severely anemic surgery patients. It is not approved for human use in the United States, or any other country. On July 31, 2002, Biopure submitted a biologic license application ("BLA") to the U.S. Food and Drug Administration ("FDA") seeking regulatory approval to market Hemopure in the United States for patients undergoing orthopedic surgery (the "Hemopure BLA").

3. This action arises as a result of the Defendants' issuance of and making of numerous public statements during the Class Period regarding Biopure, Hemopure, the Hemopure BLA, and Biopure's proposed clinical trials for use of Hemopure for trauma victims (the "Trauma Clinical Trials"). As detailed herein, those statements by the Defendants were false or materially misleading because of the omission therefrom, and because of Defendants' failure to publicly disclose, communications to Biopure from the FDA in March, 2003, in which the FDA expressed safety concerns about Hemopure. Those safety concerns arose from adverse event data from Biopure's Phase III orthopedic

surgery trial for Hemopure, which had been submitted by Biopure to the FDA as part of the Hemopure BLA. As the FDA advised the Defendants in March, 2003, those safety concerns caused the FDA to place a clinical hold on the Trauma Clinical Trials, which meant that the FDA refused to permit Biopure to conduct Biopure's proposed clinical trials for use of Hemopure for trauma victims.

4. The Class Period begins on March 17, 2003, when Biopure filed its quarterly report on Form 10-K with the SEC. To the best of Plaintiffs' knowledge, that was the first time, after the Defendants' receipt of the above-referenced communication from the FDA expressing safety concerns about Hemopure, that the Defendants made a public statement regarding Biopure, Hemopure, the Hemopure BLA or the Trauma Clinical Trials.

5. The Class Period ends on December 24, 2003. As detailed below, on that date, after the close of trading, Biopure issued a press release in which it disclosed to the investing public, for the first time, the FDA's communication to Biopure, in March, 2003, of the FDA's safety concerns regarding Hemopure and the FDA's refusal to allow Biopure to conduct the Trauma Clinical Trials because of those safety concerns. Significantly, in that December 24, 2003 Press Release, it was also disclosed that the Defendants Biopure, Moore and Richman had received a "Wells Notice" from the staff of the Securities and Exchange Commission (the "SEC") which advised those Defendants that the staff of the SEC had preliminarily determined to recommend to the SEC that the SEC bring civil proceedings against them, because they had made deceptive statements regarding Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials during the Class Period, because their statements during the Class Period did not disclose that in March,

2003, the FDA had expressed safety concerns about Biopure and, due to those safety concerns, had placed a clinical hold on the Trauma Clinical Trials.

6. As demonstrated herein, the Defendants' false, misleading and deceptive public statements regarding Biopure, Hemopure, the Hemopure BLA, and the Trauma Clinical Trials throughout the Class Period significantly artificially inflated the price of Biopure stock throughout the Class Period and caused the Plaintiffs and the members of the Class to be damaged.

JURISDICTION AND VENUE

7. This Court has jurisdiction of this action pursuant to Section 27 of the Exchange Act (15 U.S.C. §78aa), and 28 U.S.C. §§1331 and 1337.

8. This action arises under and pursuant to Section 10(b) of the Exchange Act (15 U.S.C. §78j(b)), Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5) and Section 20A of the Exchange Act (15 U.S.C. §78t-1).

9. Venue is proper in this District pursuant to Section 27 of the Exchange Act and 28 U.S.C. §1391(b). Lead Plaintiff resides in this District, Biopure's principal place of business is located in this District and most of the acts complained of herein occurred in this District.

10. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephonic communications and the facilities of the NASDAQ, a national securities exchange.

PARTIES

11. Lead Plaintiff Ronald Erickson ("Lead Plaintiff") resides in Massachusetts. As detailed in the Certification of the Lead Plaintiff, previously filed in this action (and incorporated herein by reference), the Lead Plaintiff purchased 75,000 shares of Biopure common stock during the Class Period. The Lead Plaintiff did not sell any Biopure common stock during the Class Period.

12. Plaintiff Stuart Gottlieb, as detailed in his Certification attached hereto (and incorporated herein by reference), purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

13. Plaintiff John G. Esposito, Jr., as detailed in his Certification, previously filed in this action (and incorporated herein by reference), purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

14. Plaintiff Emily A. Bittman, as detailed in her Certification attached hereto (and incorporated herein by reference), purchased shares of Biopure common stock contemporaneously with the sales of Biopure stock by defendants during the Class Period.

15. Defendant Biopure is a Delaware corporation, with its headquarters in Cambridge, Massachusetts.

16. The Defendant Thomas A. Moore ("Moore") was, at all relevant times, Biopure's President and Chief Executive Officer, and a director of Biopure.

17. The Defendant Carl W. Rausch ("Rausch") was, at all relevant times, Biopure's Vice Chairman and Chief Technical Officer, and a director of Biopure.

18. The Defendant Ronald F. Richards ("Richards") was, at all relevant times, Biopure's Chief Financial Officer and Senior Vice President - Business Development.

19. The Defendant Howard P. Richman ("Richman") was, during some of the relevant time period, Biopure's Senior Vice President of Regulatory Affairs and Operations.

20. The Defendant Charles A. Sanders ("Sanders") was, at all relevant times, a director of and Chairman of the Board of Directors of Biopure.

21. The Defendant J. Richard Crout ("Crout") was, at all relevant times, a director of Biopure. Previously, he was a division chief for the FDA.

22. The Defendants Moore, Rausch, Richards, Richman, Sanders and Crout are hereinafter sometimes collectively referred to as the "Individual Defendants."

23. The Defendants Biopure, Moore, Rausch, Richards, Richman, Sanders and Crout are hereinafter sometimes collectively referred to as the "Defendants."

BACKGROUND INFORMATION REGARDING BIOPURE

24. The following statements, from Management's Discussion and Analysis of Financial Condition and Results of Operations, January 31, 2003, filed by Biopure with the SEC on March 17, 2003 in its quarterly report on Form 10-Q for the Quarterly Period ended January 31, 2003 (the "January 2003 10-Q"), provides a brief summary of the history of Biopure:

> Since its founding in 1984, Biopure has been primarily a research and development company focused on developing Hemopure, our oxygen therapeutic for human use, and obtaining regulatory approval in the United States. Our research and development expenses have been devoted to basic research, product development, process development, pre-clinical studies, clinical trials and filing a BLA with the FDA....
>
> * * *

Biopure is a leading developer, manufacturer and supplier of pharmaceuticals called oxygen therapeutics. Using our patented and proprietary technology, we have developed and manufacture two products. Hemopure is a first-in-class product for human use that is approved in South Africa for the treatment of acutely anemic surgical patients as an alternative to red blood cell transfusion. On July 31, 2002, we submitted a biologic license application (BLA) to the FDA seeking regulatory approval to market Hemopure in the United States for a similar indication in patients undergoing orthopedic surgery....

* * *

Since inception, we have devoted substantially all of our resources to our research and development programs and manufacturing. We have been dependent upon funding from debt and equity financing, strategic alliances and interest income. We have not been profitable since inception and had an accumulated deficit of $392,713,000 as of January 31, 2003. We expect to incur additional operating losses over the next several years in connection with clinical trials, preparation of a marketing application for Hemopure in Europe and other markets and pre-marketing expenditures for Hemopure....

* * *

The completed Phase III orthopedic surgery trial cost approximately $37,000,000 over the four years from protocol development to final report. These trial costs include costs incurred at nearly 50 hospitals, trial site monitoring, data management, regulatory consulting, statistical analysis, medical writing and clinical materials and supplies as well as Company personnel engaged in these activities. Costs incurred in filing the BLA include Company personnel and payments to third parties for manufacturing process documentation, medical consultants, regulatory consultants, integrating the safety and efficacy data bases for all clinical trials and pre-clinical studies. Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation....

25. On July 31, 2002, Biopure submitted the Hemopure BLA to the FDA, seeking regulatory approval for the use and sale of Hemopure in the United States for patients undergoing orthopedic surgery (the "Hemopure BLA"). As part of the usual procedure in seeking such approval, Biopure submitted to the FDA, as part of the Hemopure BLA, data from the Phase III clinical trials which it had conducted for the use of Hemopure for patients undergoing orthopedic surgery, including adverse event data.

26. In September, 2002, Biopure received a grant from the United States Department of the Army for the purpose of conducting clinical trials of Hemopure for the treatment of certain trauma patients. In Biopure's Annual Report for its fiscal year 2002, filed with the SEC on Form 10-K on January 29, 2003, the Defendants said: **"The Company has identified trauma as its next clinical development priority and is working with a committee of independent civilian and military trauma experts to broaden its trauma program."** (Emphasis added.)

27. In light of the history and the nature of business of Biopure, the most critical and material information about Biopure during the Class Period was the status of the Hemopure BLA, including all facts which bore on when the FDA would rule on the Hemopure BLA and the likelihood that the FDA would (or would not) approve the Hemopure BLA, thereby approving (or not approving) Biopure's sale of Hemopure in the United States for use with orthopedic surgery patients. In addition, information regarding the Trauma Clinical Trials, and particularly the FDA's views and position regarding whether the Trauma Clinical Trials would be allowed to go forward, was also highly material information regarding Biopure during the Class Period.

SUBSTANTIVE ALLEGATIONS

28. In March, 2003, the Company submitted to the FDA a "Trauma Study Protocol," in which the Company advised the FDA of its intention to conduct a Phase II clinical study of Hemopure for use in trauma victims.

29. In March, 2003, Immediately after Biopure's March, 2003, submission to the FDA of the Trauma Study Protocol for a Phase II clinical trial of Hemopure for the treatment of trauma patients, the FDA informed the Defendants that the proposed clinical trial could not go forward. **The FDA advised the Defendants that it had placed a clinical hold on their proposed Phase II clinical trial of Hemopure for the treatment of trauma patients due to safety concerns arising from the FDA's review of adverse event data from the Company's Phase III orthopedic surgery trial, which was submitted in the Hemopure BLA.**

30. That communication, in March, 2003, from the FDA to the Defendants, was highly material adverse information about Biopure, which any reasonable investor would have wanted to know in making an investment decision regarding Biopure. That communication would have significantly affected the total mix of information available to an investor in Biopure common stock.

31. The FDA's safety concerns, as expressed in its March, 2003, communication, put Defendants on notice that FDA approval of the Hemopure BLA, which would allow the first commercial distribution of Hemopure in the United States, was in jeopardy and in serious doubt and that the FDA's decision on the Hemopure BLA would, unquestionably, be delayed beyond the time frames previously communicated by Defendants to the investing public. Nevertheless, over the next nine months, throughout the Class Period,

despite numerous opportunities in press releases, analyst conferences and conference calls and SEC filings, Defendants intentionally failed to disclose any of these adverse material facts to the investing public. Indeed, as detailed below, the Company's periodic statements regarding the Hemopure BLA and the Trauma Clinical Trials, during the Class Period, were false and deceptive, and they materially misled investors concerning the status of the Hemopure BLA and the status of the Trauma Clinical Trials.

32. On December 24, 2003, Biopure issued a Press Release (the "December 24, 2003 Press Release"). A copy of the December 24, 2003 Press Release is attached hereto as Exhibit A and incorporated herein by reference.

33. The December 24, 2003 Press Release stated, in part, as follows:

> CAMBRIDGE, Mass., Dec 24, 2003 ... Biopure Corporation (BLUR) reported that on December 22, 2003, it received a "Wells Notice" from the staff of the Securities and Exchange Commission (SEC) indicating the staff's preliminary decision to recommend that the SEC bring a civil injunctive proceeding against the company.... The company's chief executive officer [the Defendant Moore] and its former senior vice president of Regulatory and Operations [the Defendant Richman] also received Wells Notices.
>
> ... the notices relate to the company's disclosures concerning its communications with the Food and Drug Administration (FDA) about a trauma study protocol the company submitted to the Agency in March 2003 and about the company's biologics license application (BLA) for Hemopure (R) [hemoglobin glutamer - 250 (bovine)]....
>
> Biopure submitted the trauma protocol for a Phase II clinical trial of Hemopure for the treatment of hemorrhagic shock casualties in the hospital setting, where red blood cell transfusions are available....
>
> After the in-hospital trauma protocol was submitted to the FDA...**the Agency placed a clinical hold on the proposed trauma trial due to safety concerns. The FDA referred to a review of adverse event data from the company's Phase**

> **III orthopedic surgery trial, which was submitted in the BLA**....(emphasis added)
>
> In May 2003, Biopure responded to the FDA's clinical hold and also filed the response as a BLA amendment because it discussed data previously submitted with the BLA. That amendment resulted in the FDA extending its BLA review period up to 90 days, as previously announced on May 30, 2003.... After the company's responses, the FDA has twice declined to lift the clinical hold, most recently in a letter dated July 30, 2003. This letter is separate from the FDA complete response letter Biopure received on that date in response to its BLA for orthopedic surgery. The questions in the FDA's trauma letter were the same as some of the questions in the BLA complete response letter....

34. The December 24, 2003 Press Release informed the investing public, for the first time, about the FDA's safety concerns regarding Hemopure as a result of adverse event data from Biopure's Phase III clinical trial for its Hemopure BLA, and the fact that, in light of those safety concerns, the FDA had placed a clinical hold on the Trauma Clinical Trials, which was communicated to the Defendants by the FDA, in March 2003; the serious impact those safety concerns had and were continuing to have on the prospects of the Hemopure BLA being approved by the FDA; and the delays those safety concerns would cause in the FDA's decision regarding the Hemopure BLA.

35. The December 24, 2003 Press Release informed the investing public, for the first time, that due to the FDA's safety concerns regarding Hemopure as a result of adverse event data from Biopure's Phase III clinical trial for its Hemopure BLA in March 2003; the FDA had, in March 2003, placed a clinical hold on the Trauma Clinical Trials.

36. The December 24, 2003 Press Release informed the investing public, for the first time, that the Defendants' public statements during the Class Period regarding

Biopure, the Hemopure BLA and the Trauma Clinical Trials had been false, deceptive and misleading.

37. On January 29, 2004, Biopure filed its Annual Report for its fiscal year ended October 31, 2003 with the SEC on Form 10-K/A (hereinafter the "2003 10-K"). The 2003 10-K was signed by all of the Individual Defendants except Richman. In the 2003 10-K the Defendants disclosed some additional adverse material information concerning the SEC's investigation and Biopure's communications with the FDA during the Class Period. Specifically, the Defendants disclosed the following in the 2003 10-K:

> **13. Litigation and Subsequent Events**
>
> *SEC Investigation.* During the fourth quarter of fiscal 2003, the Company was notified of a confidential investigation by the Securities and Exchange Commission (SEC). On December 22, 2003, the Company, its Chief Executive Officer and its former Senior Vice President, Regulatory and Operations received "Wells Notices" from the staff of the SEC stating the staff's preliminary determination to recommend that the SEC bring a civil injunctive proceeding against the Company and the individuals. Biopure and the individuals responded in writing to the notices on January 9, 2004. The staff is continuing to gather information.
>
> Biopure believes the notices relate to Company disclosures concerning communications with the FDA about a clinical hold imposed on a clinical study protocol the Company submitted to the agency in March 2003 and the status of the Company's BLA. In March 2003, the Company filed a proposed protocol for a Phase II clinical trial in trauma patients in a hospital setting. The FDA put the protocol and its related investigational new drug application (IND) on "clinical hold," meaning the trial could not begin as proposed. The FDA cited safety concerns based on a preliminary review of data from the Company's trial in patients undergoing orthopedic surgery. After the Company responded in two written submissions, the clinical hold was reasserted twice in writing, most recently on July 30, 2003. The Company did not disclose the clinical hold because the Company did not consider correspondence with the agency about data interpretation in the development of a

> protocol to be material, notwithstanding the references to data in the BLA. The staff's investigation also concerns the Company's disclosures concerning the FDA's review of the BLA, after receipt of the complete response letter dated July 30, 2003. The Company has been cooperating throughout the investigation with the SEC staff. At this time, the Company cannot estimate what impact, if any, this inquiry may have on its financial position or results of operations.

38. The FDA's safety concerns regarding Hemopure as a result of adverse event data from Biopure's Phase III clinical trial for its Hemopure BLA, and the fact that, in light of those safety concerns, the FDA had placed a clinical hold on the Trauma Clinical Trials, which was communicated to the Defendants by the FDA from March 2003 through July 30, 2003, are hereinafter sometimes referred to as the "FDA's Safety Concerns."

THE MATERIALLY FALSE AND MISLEADING STATEMENTS ISSUED BY AND MADE BY THE DEFENDANTS DURING THE CLASS PERIOD

39. Throughout the Class Period the Defendants repeatedly issued and made statements to the investing public about Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials. These statements were contained in Biopure's filings with the SEC; in press releases issued by Biopure (some of which contained statements by the Defendant Moore); and in presentations and telephone conferences by Moore and other Individual Defendants to securities analysts, investment advisors and other members of the investing public.

40. As demonstrated and detailed below, the Defendants' statements during the Class Period regarding Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials were false, deceptive and misleading because of the Defendants' failure to disclose

the FDA's Safety Concerns. Some of the Defendants' false, deceptive and misleading statements are detailed below.

41. In the January 2003 Form 10-Q, the Defendants, while purporting to disclose risks faced by Biopure and its shareholders, made the following false and deceptive statement regarding its Phase III Hemopure clinical trial:

> *If We Fail to Obtain FDA Approval We Cannot Market Hemopure in the United States*
>
> We will not be able to market Hemopure in the United States until we receive FDA approval. We have filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002. **We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on** the design and efficacy and **safety endpoints required for approval of products such as Hemopure for use in surgical indications.**[1] (Emphasis added.)

42. The statement quoted in the preceding paragraph, from the January 2003 10-Q, including the portion of the quotation in the footnote, is hereinafter referred to as the "False and Deceptive Statement Regarding '*If We Fail to Obtain FDA Approval*.'"

43. The False and Deceptive Statement Regarding '*If We Fail to Obtain FDA Approval*' was false, deceptive and misleading in light of the FDA's Safety Concerns and the Defendants' failure to disclose the FDA's Safety Concerns.

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[1] After making that false and misleading statement, the Defendants added this "proviso:"

> However, the FDA could change its view, require a change in study design or require additional data or even further clinical trials, including trials for indications other than those for which the pending applications seeks approval, prior to approval of Hemopure. The FDA could refuse to grant a marketing authorization. Trials are expensive and time-consuming. Obtaining FDA approval generally takes years and consumes substantial capital resources with no assurance of ultimate success.

44. During the Class Period, the Defendants filed registration statements with the SEC, in each of which the Defendants repeated the False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval,*" *verbatim* or almost *verbatim*, and each of which contained the false statement emphasized in the above quoted False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval.*" Those registration statements were false, deceptive and misleading because of the Defendants' failure to disclose the FDA's Safety Concerns. Those registration statements, all of which were signed by all of the Individual Defendants, except Richman, were:

a. Post-Effective Amendment No. 2 to Form S-3 registration statement filed with the SEC on April 11, 2003;

b. Post-Effective Amendment No. 1 to Form S-3 registration statement filed with the SEC on April 16 2003;

c. Form S-3 Registration Statement filed with the SEC on June 19, 2003; and

d. Amendment No. 1 to Form S-3 registration statement filed with the SEC on July 2, 2003.

45. The January 2003 Form 10-Q, the Defendants also contained the following misleading and deceptive statements concerning the Company's Hemopure BLA:

> Research and development expenses continue to include amounts for support of the BLA review process including responding to FDA inquiries, preparing for and participating in FDA inspections of facilities and documentation and preparing for a possible FDA Advisory Panel presentation. These BLA support costs were $2,232,000 for the first fiscal quarter of 2003 and are expected to continue at approximately the same level ***until the middle of this calendar year, when the Company is hopeful that it will receive action by the FDA on the BLA.***

* * *

> ***If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.*** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure... . (Emphasis added.)

46. The January 2003 Form 10-Q was signed by the Defendant Richards. Furthermore, as required by SEC Rules 13a-14(a) and (b) and 15d-14(a) and (b), promulgated pursuant to the Exchange Act, the January 2003 Form 10-Q contained certifications by the Defendant Moore, as the Chief Executive Officer of Biopure and the Defendant Richards, as the Chief Financial Officer of Biopure, in which they each certified:

> 1. I have reviewed this quarterly report on Form 10-Q of Biopure Corporation;

and in which they then falsely certified:

> 2. Based on my knowledge, **this quarterly report does not** contain any untrue statement of a material fact or **omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading** with respect to the period covered by this quarterly report; [emphasis added]

47. The Defendants Moore and Richards also certified that Biopure and they had designed "disclosure controls and procedures" which would have ensured that they would have learned of the FDA's Safety Concerns, so they could have been timely and properly disclosed to the investing public in the January 2003 Form 10-Q. Specifically, Moore and Richards certified that:

> 4. The registrant's other certifying officers and I are responsible for establishing and maintaining disclosure

> controls and procedures (as defined in Exchange Act Rules 13a - 14 and 15d -14)[2] for the registrant and we have:
>
> > a) designed such disclosure controls and procedures to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this quarterly report is being prepared;
> >
> > b) evaluated the effectiveness of the registrant's disclosure controls and procedures as of a date within 90 days prior to the filing date of this quarterly report (the "Evaluation Date"); and
> >
> > c) presented in this quarterly report our conclusions about the effectiveness of the disclosure controls and procedures based on our evaluation as of the Evaluation Date...

48. The "conclusions about the effectiveness of the disclosure controls and procedures" referenced in the above quoted certification by Moore and Richards, set forth in the January 2003 Form 10-Q, were as follows:

> (a) Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-14(c) and 15d-14(c) under the Securities Exchange Act of 1934, as

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[2] Exchange Act Rules 13a - 14(c) and 15d -14(c) define "disclosure controls and procedures" as follows:

> ...controls and other procedures of an issuer that are designed to ensure that information required to be disclosed by the issuer in the reports that it files or submits under the Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. **Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Act is accumulated and communicated to the issuer's management, including its principal executive officer or officers and principal financial officer or officers...** (Emphasis added.)

> amended (the "Exchange Act")) within 90 days of the filing date of this Quarterly Report on Form 10-Q (the "Evaluation Date"). Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded as of the Evaluation Date that our disclosure controls and procedures were effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized and reported within the time periods specified in Securities and Exchange Commission rules and forms.

49. On March 25, 2003, Biopure issued a press release announcing that it had raised $13.4 million in gross proceeds through the sale of 5,548,480 shares of its common stock at $2.42 per share. The press release contained the following misleading and deceptive statements regarding the Hemopure BLA and the Trauma Clinical Trial:

> Hemopure(R) ... is approved in South Africa for the treatment of adult surgical patients who are acutely anemic and for the purpose of eliminating or reducing the need for allogenic red blood cell transfusion in these patients. **Biopure's application to market Hemopure in the United States for a similar indication in adult patients undergoing elective orthopedic surgery is currently being reviewed by the U.S. Food and Drug Administration...**
>
> ... The previously announced $4.9 million in FY02/03 Congressional appropriations administered through the U.S. Army and anticipated $4 million in U.S. Navy funding from a Cooperative Research and Development Agreement (CRADA) for clinical trials of Hemopure in trauma are project-specific funds independent from Biopure's reported cash on hand. **Completion of the pivotal RESUS clinical trial of Hemopure in trauma is contingent upon further funding**, $908,900 of the Army funding is from Grant DMAD17-02-1-0697, for which the U.S. Army Medical Research Acquisition Activity, 820 Chandler Street, Fort Detrick, MD 21702-5014 is the awarding and administering acquisition office. (Emphasis added.)

50. On April 24, 2003, Biopure and Moore issued a press release which stated, *inter alia*:

> CAMBRIDGE, Mass., April 24/PRNewswire-FirstCall/ – Biopure Corporation (Nasdaq: BPUR) has appointed Ketchum

> to provide public relations support and LifeBrands to provide medical education support for Biopure's investigational oxygen therapeutic, Hemopure(R)...
>
> The U.S. Food and Drug Administration is currently reviewing Biopure's biologic license application "BLA" to market Hemopure in the United States. Ketchum and LifeBrands will provide communications support for Hemopure and handle educational activities surrounding the anticipated product introduction in orthopedic surgery and the clinical development of other potential indications in trauma, ischemia and cancer.
>
> "We look forward to successful partnerships with Ketchum and LifeBrands as we prepare to commercialize this first-in-class product," **said Thomas A. Moore, President and Chief Executive Officer of Biopure. "Based on our interactions with the FDA and the guidelines in the Prescription Drug Users Fee Act, we're hopeful the agency will complete its review of our marketing application mid-year."**
>
> Biopure is seeking FDA approval to market Hemopure for the treatment of acutely anemic adult patients undergoing orthopedic surgery, and for the purpose of eliminating or reducing the need for red blood cell transfusions in these patients. As part of the BLA review process, the FDA has completed its inspections of Biopure's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. Biopure has responded to all questions raised by the FDA during the inspections and has resolved all previous manufacturing documentation issues with the FDA. Hemopure continues to be manufactured and is available for shipment. (Emphasis added.)

51. As first disclosed by the Defendants in the December 24, 2003 Press Release, in May 2003 Biopure responded to the FDA's Safety Concerns, as they impacted on the Hemopure BLA, by filing a BLA amendment. In response to the filing of the BLA amendment, the FDA extended its BLA review period an additional 90 days, to August 29, 2003. As detailed below, while the Defendants disclosed to the investing public that the FDA had extended its BLA review period an additional 90 days, to August 29, 2003, those

disclosures were false, deceptive and misleading, because they did not disclose that the BLA amendment and the FDA's extension of the BLA review period was precipitated by and caused by the FDA's Safety Concerns.

52. As first disclosed by the Defendants in the December 24, 2003 Press Release, in May 2003 Biopure responded to the FDA's Safety Concerns which had caused the FDA to place a clinical hold on the Trauma Clinical Trials. After those responses, the FDA, on two occasions, the last in a letter dated July 30, 2003, refused to lift its clinical hold on the Trauma Clinical Trials. As detailed below, during that time period the Defendants made statements to the public regarding the Trauma Clinical Trials, all of which were false, misleading and deceptive, because in those statements the Defendants never disclosed that in March 2003 the FDA had placed a clinical hold on the Trauma Clinical Trials because of the FDA's Safety Concerns, and that the FDA had repeatedly thereafter refused to lift its clinical hold on the Trauma Clinical Trials because of the FDA's Safety Concerns.

53. On May 22, 2003, Biopure issued a press release in which the Defendants made the following misleading and deceptive statements regarding the Hemopure BLA and the Trauma Clinical Trials:

> Based upon FDA performance goals and guidelines in the Prescription Drug User Fee Act (PUDFA), **Biopure is hopeful that in mid 2003 the FDA will complete its review and act on Biopure's biologic license application (BLA) to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery.** As part of this review, the agency has inspected the company's manufacturing and data-handling facilities and has audited its contract research partners and several clinical sites in the United States and South Africa. **Biopure has responded to all questions raised by the FDA to date.** (Emphasis added).

> The U.S. Army has notified Biopure that the company will receive approximately $4 million in FY03 Congressional funding, in addition to a $908,900 grant previously awarded in FY02 [footnote omitted], designated to fund trauma trials of Hemopure in emergency rooms and ambulances. In addition, in March 2003 Biopure and the Naval Medical Research Center (NMRC) signed a collaborative research and development agreement (CRADA) to help fund and conduct a pivotal trauma trial of Hemopure. Participation in this collaborative effort is estimated to cost the NMRC at least $4 million. Biopure will contribute an estimated $8.7 million, of which at least $643,000 will be provided during the first year. Biopure is preparing for a Phase IIa in-hospital trauma trial, and the study protocols for Phase IIb/pivotal pre-hospital trial are currently under scientific review by the NMRC.

54. On May 22, 2003, the Defendants Biopure, Moore, Richards and Richman participated in a telephonic conference call for analysts and institutional investors. As described below, a live audio webcast of the conference call was available to all members of the investing public. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit B, and incorporated herein by reference. That conference call is hereinafter referred to as the "May 22 Conference Call."

55. During the May 22 Conference Call, the Defendants made statements and answered questions from public participants, about Biopure, the Hemopure BLA and the Trauma Clinical Trials, which were false, deceptive and misleading. For example, the Defendant Moore made the following false, deceptive and misleading statements during the May 22 Conference Call:

> a. "...we continue to be very hopeful of an [FDA] response on our [biologic] license application by mid-year or sooner, and **we continue to not be aware of any major issues with that application at this time....**"
>
> b. "On FDA I'll just reiterate, I guess, at our last quarter we ... had answered all FDA questions and **we were unaware of**

> **any major issues. Fundamentally we're in the same place now.**"
>
> c. **"We continue to say we are not aware of anything that would cause undue delay** [in receiving a response from the FDA to the Hemopure BLA]..."

(Exhibit B at 1 and 2, emphasis added).

56. Those statements were false, deceptive and misleading in light of the FDA's Safety Concerns and the Defendants' failure to disclose the FDA's Safety Concerns. Those statements were made directly by the Defendants Moore and Biopure, and they also constituted statements by Richman and Richards, in light of the fact that, while participating in the May 22 Conference Call, they acquiesced in and did not, in any way, correct those statements which they knew to be false, deceptive and misleading.

57. All of the statements made by the Defendants during the May 22 Conference Call were available to all members of the investing public. Specifically, as stated in the May 23, 2003 Press Release:

> Biopure President and CEO Thomas A. Moore will host a conference call at 4:30 p.m. EDT on Thursday, May 22, 2003, to briefly review the company's activities and financial position. The dial-in numbers for analysts and institutional investors are 1-800-387-5428 (US/Canada) and 1-706-634-1328 (International).
>
> A live webcast of the conference call will be available from the investors section of Biopure's web site at www.biopure.com and will be archived for 30 days. The webcast can also be heard by individual investors at www.companyboardroom.com and by institutional investors who subscribe to StreetEvents at www.streetevents.com. An audio replay of the conference call will be available from approximately 7:30 p.m. EDT, May 22, 2003, until midnight May 30, 2003. To access the replay, dial 1-800-642-1687 (US/Canada) or 1-706-645-9291 (International/Local) and Reference Conference ID number 438897.

58. On May 30, 2003, the Company issued a press release (the "May 30 Press Release") announcing that the FDA had notified Biopure that it had extended the time for it to act on the Hemopure BLA for an additional 90 days, until August 29, 2003. Biopure explained this action by the FDA, in the May 30 Press Release, as follows:

> Biopure submitted its BLA on July 31, 2002. Under FDA performance goals in the Prescription Drug User Fee Act (PDUFA III), the agency has up to 10 months from the submission date to review and act on the BLA, making the original action due date June 1, 2003. As part of the normal review process, Biopure has responded to FDA questions regarding the application. The agency has classified the latest responses submitted in mid-May 2003 as additional analyses of previously submitted data, which under FDA standard operating procedures automatically provides the agency up to three months beyond the original action due date to review the data. This type of action is not unusual–the last 11 standard BLAs accepted for review by the FDA have undergone a 13-month review.

59. In the May 30 Press Release, the Defendant Moore made the following statement regarding the FDA's action:

> "We're very pleased with the FDA's progress in reviewing our application," said Biopure President and CEO Thomas A. Moore. "We continue to work closely with the agency toward a final decision that will allow us to make Hemopure available as an alternative to red blood cell transfusion. We're also continuing our preparations to roll out the product to leading orthopedic surgery centers following approval."

60. In the May 30, 2003 press release, Biopure also announced that it would hold a conference call on May 30, 2003 at 3 pm ET, at which it "will discuss the regulatory status of Hemopure..." (hereinafter, the "May 30 Conference Call"). Like the May 22 Conference Call, analysts and institutional investors could participate in the May 30 Conference Call and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of the May 30 Conference Call,

entitled *Biopure Corporation Conference Call to Discuss the Regulatory Status of Hemopure*, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit C, and incorporated herein by reference.

61. The Defendants Moore, Richman and Richards participated in the May 30 Conference Call on behalf of Biopure. As reflected in the transcript, two of the analysts participating in the call expressed concern about the fact that the FDA had extended the time for it to act on the Hemopure BLA for an additional 90 days, until August 29, 2003. They asked pointed questions regarding the reasons for that delay by the FDA, to which the Defendants gave false, deceptive and misleading responses. Some of that colloquy was as follows:

> **Richard Adams** - *Bennett Lawrence - Analyst*
>
> ...why are you still having to provide information to the FDA? You said mid-May there was a resubmission of some sort. Why nine and a half months after the original BLA was submitted are you still having to provide information?
>
> **Thomas A. Moore** – *Biopure - CEO and President*
>
> ...This mid-May submission was some additional analysis which we provided on data that was already in the BLA. At the time, we didn't consider it a major amendment to the BLA but the FDA looked at that as a reason to extend it...
>
> *** * ***
>
> **Richard Adams** – *Bennet Lawrence - Analyst*
>
> ...but it would seem that for there to be some sort of submission that would extend the PDUFA date another two months, it would have to be something material. And I guess I'm just surprised that nothing was disclosed in mid-May when this additional submission was made.
>
> **Thomas A. Moore** – *Biopure - CEO and President*

To be clear, we were simply responding to a new set of questions from FDA. It did not involve any new data. And so frankly, it was well within the range of other questions we've answered in the past. When we made that response, we didn't characterize it as a major amendment to the BLA...

* * *

Gabe Hoffman - *Occipital Capital - Analyst*

...Could you please be a little more specific in terms of – the company has submitted additional analyses of previously submitted data. Could you be a little more specific as to what elements of the clinical data that that refers to?

Thomas A. Moore – *Biopure - CEO and President*

I can't be a lot more specific.

Gabe Hoffman – *Occipital Capital - Analyst*

I mean, is it safety, is it statistical procedure, is it some auditing of patient records? I mean, could you just be somewhat more specific?

Thomas A. Moore – *Biopure - CEO and President*

Well, all patient records have been audited and so all that's been done, so that's not at issue as far as I know anyway.

Gabe Hoffman – *Occipital Capital - Analyst*

Or merely is it formatting or you know?

Thomas A. Moore – *Biopure - CEO and President*

It's actually – it was a dialogue really about how to look at the clinical data. As you know, there are various analyses used to look at our efficacy and safety data and we just had a dialogue about the different ways you could look at the analyses that are performed on the data. And that's really as far as I want to characterize it.

Gabe Hoffman - *Occipital Capital - Analyst*

> But could you just give us maybe a broader ballpark sense as to – you know, just a broad area that it is – is there a specific area that it's in that's a broad area that maybe you could characterize it? That's more specific than just it's the clinical data?
>
> **Thomas A. Moore** – *Biopure - CEO and President*
>
> Well, I mean, all the clinical data has to do with safety and efficacy. That's the only thing in measure in these clinicals. And so, the dialogue is over those clinical and safety and efficacy data. And again, we have answered some questions on a pretty broad basis. When I talk about it as how to look at the clinical analysis, it's exactly what it was. So I think that's as far and as specific as I really want to be at this point.
>
> *** * ***
>
> **Roberto McNuln** - *Bridger Capital - Analyst*
>
> To get some more information about the additional data asked for – given your assessment that the questions asked were very broad, I'm still unclear as to why then at this late in the date it would require a three month delay. I would understand if the questions were very detailed that the FDA would ask for – would take that additional time. But your assessment of the questions being very broad makes me want to get some more detail about that.
>
> **Thomas A. Moore** – *Biopure - CEO and President*
>
> ...the FDA chose to look at this as a major amendment to the BLA...if we submit new information about any aspect of the product or new analysis about any aspect of the product, whether it's pivotal to their decision or not, they can decide that that's a reason to go for the extension. So I'm not sure whether or not the data we submitted, we did not submit any new data, whether that was a reason for the extension of whether the echo simply needed an extension, period.

(Exhibit C at 3-5 and 7, emphasis added).

62. Those statements were false, deceptive and misleading in light of the FDA's Safety Concerns and the Defendants' failure to disclose the FDA's Safety Concerns.

Those statements were made directly by the Defendants Moore and Biopure, and they also constituted statements by Richman and Richards, in light of the fact that, while participating in the May 30 Conference Call, they acquiesced in and did not, in any way, correct those statements which they knew to be false, deceptive and misleading.

63. In June 16, 2003, Biopure filed its quarterly report on Form 10-K with the SEC for the quarter end April 30, 2003 (the "April 2003 10-Q"). It contained the False and Deceptive Statement Regarding "*If We Fail to Obtain FDA Approval*" and the following false and deceptive statement:

> ***If the FDA were to grant marketing approval for Hemopure this calendar year, we anticipate that we would have material revenues from this project in fiscal 2004.*** We do not anticipate that we will attain profitability, however, until we are able to increase our manufacturing capacity. There are substantial risks and uncertainties relating to whether and when we will obtain FDA approval for Hemopure... . (Emphasis added.)

64. The April 2003 10-Q was signed by the Defendant Richards. Furthermore. it contained the identical false certifications, signed by the Defendants Moore and Richards, which are contained in the January 2003 Form 10-Q, which certifications are quoted above.

65. On July 23, 2003, Biopure issued a press release announcing that it has raised $17.2 million in gross proceeds through the sale of 3,083,000 shares of its common stock at $5.58 per share.

66. On August 1, 2003, Biopure issued a press release (the "August 1 Press Release") in which it disclosed that the FDA was seeking additional information in

connection with the Hemopure BLA and that the FDA had suspended its review clock on the Hemopure BLA. Specifically, the August 1 Press Release said:

> CAMBRIDGE, Mass., Aug. 1, 2003 /PRNewswire-FirstCall via COMTEX/ – Biopure Corporation (BPUR) announced today that the U.S. Food and Drug Administration (FDA) has completed its review of the company's biologic license application (BLA) for Hemopure(R) [hemoglobin gulatmer - 250 (bovine)] and issued a letter requesting additional information. The letter focuses primarily on clarification of clinical and preclinical data and includes some comments on labeling. It does not request additional clinical trials. Biopure has applied to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients.
>
> With 30 days remaining in the original BLA review cycle, the issuance of the letter has suspended the FDA review clock until Biopure submits a complete response.
>
> "We're encouraged that the FDA has finished its review and provided comprehensive feedback in advance of the formal action due date. By maintaining thirty days on the review clock, the FDA is encouraging us to work with them to complete the approval process as quickly as possible," said Biopure President and CEO Thomas A. Moore. "We'll work with the Agency to address the remaining questions and will provide our answers as expeditiously as possible."

67. The August 1 Press Release was false, deceptive and misleading because the Defendants omitted from it the FDA's Safety Concerns. The August 1 Press Release artificially inflated the price of Biopure's common stock.

68. The marketplace, not knowing of the FDA's Safety Concerns, responded positively to the August 1 Press Release. On August 1, 2003, the price of Biopure common stock closed at $7.30 per share, up $1.33 per share, or 22%, over its close at $5.97 per share on July 31, 2003. Biopure's stock traded as high as $9.03 per share on August 1, 2003, on volume of almost 7 million shares.

69. Thereafter the price of Biopure stock continued to rise, closing on August 20, 2003 at $8.12 per share.

70. On August 21, 2003, Biopure issued a press release which included the following statements concerning the FDA's review of the Company's Hemopure BLA:

> On July 30th, the FDA sent Biopure a letter stating that the agency has completed its review of the company's BLA to market Hemopure in the United States for the treatment of acutely anemic adult patients undergoing orthopedic surgery and for the elimination or reduction of red blood cell transfusions in these patients. The letter requests additional information and suspends the BLA review clock with 30 days remaining in the original review cycle. It does not request additional clinical trials. Biopure is preparing its response, which, when submitted, will restart the review clock. "We've developed many of our initial responses and so far we feel we will be prepared to answer FDA's questions," said Moore. "We have an opportunity to answer all of the Agency's remaining questions before it acts on our application, so we want to be sure we're fully meeting the FDA's needs. Therefore, we are requesting a meeting with the FDA in September. The Agency is allowing Biopure to set the agenda for this meeting, which will enable us to request any clarifications we need to complete our responses. The timing for when we'll submit our complete response to the FDA will be driven by the guidance we receive during this meeting."

71. On August 21, 2003, the Defendants Biopure, Moore, Richards and Richman participated in a telephonic conference call for analysts and institutional investors. Like the May 22 Conference Call, analysts and institutional investors could participate in the August 21 Conference Call and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit D, and incorporated herein by reference. That conference call is hereinafter referred to as the "August 21 Conference Call."

72. During the August 21 Conference Call, the Defendants made statements and answered questions from public participants, about Biopure, the Hemopure BLA and the Trauma Clinical Trials, which were false, deceptive and misleading. They also made statements in which they admitted that the statements they had been making about Biopure, the Hemopure BLA and the Trauma Clinical Trials were being believed by the marketplace and were causing the price of Biopure stock to increase. For example, the Defendant Moore made the following statements during the August 21 Conference Call:

Thomas A. Moore - *Biopure Corporation - Chief Executive Officer*

> In July we completed a public offering raising $17.2 million...In conducting this raise, Chief Financial Officers Ron Richards and I presented to 62 funds in person over a three-week period. This is the most extensive presentation of the company ever, surpassing even the effort behind the IPO launch. **Subsequent share price performance suggests we're beginning to establish an understanding of the exciting future potential for Hemopure** as both a treatment for anemia associated with surgery, and an oxygen therapeutic for use in trauma, surgical ischemias and cancer therapy.

* * *

Alan Ferguson - *3i Technology Partners - Analyst*

> Okay. Is there anything on the work the trials that the military is doing in trauma yet?

Thomas A. Moore - *Biopure Corporation - Chief Executive Officer*

> We've not initiated human clinical trials in trauma with the military or for that matter on the civilian side as yet. So, we hope to get started on that ASAP...but I don't believe human trials will begin until after we have completed our answers to the BLA.

(Exhibit D at 2 and 6, emphasis added).

73. On August 21, 2003, Biopure's stock closed at $8.25 per share.

74. On September 10, 2003 Biopure issued a press release announcing that the Defendant Moore would be making a presentation at the ThinkEquity Partners Growth Conference on September 17, 2003. As reflected in the press release, Moore's statements at that conference were made available to the investing public. The press release, in relevant part, stated as follows:

> ...Biopure Corporation (BPUR) today announced that company President and CEO Thomas A. Moore will present at the ThinkEquity Partners Growth Conference on Wednesday, September 17, 2003, at 9:30 p.m. PT. The investor conference is being held at The OMNI San Francisco from September 16-17, 2003. A live webcast of the 25-minute presentation will be available online via the Investor Relations section of Biopure's web site at www.biopure.com...An archive of the webcast will be available for at least 4 days following the event.

75. On September 17, 2003, the Defendant Moore, gave a presentation about Biopure, Hemopure and the Hemopure BLA at the ThinkEquity Partners Growth Conference at the Omni Hotel in San Francisco, California. That conference was attended by securities analysts, investment advisors and other members of the investing public. Attached hereto as Exhibit E is a transcript of Moore's statements at that conference, which are incorporated herein by reference. This transcript was transcribed by Plaintiffs' counsel's personnel, from an audio tape of the Defendant Moore's presentation, which audio tape is in the possession of Plaintiffs' counsel.

76. As reflected in Exhibit E hereto, at the ThinkEquity Growth Partners Conference, the Defendant Moore said:

> ...From a safety standpoint, our agreement with FDA was that the primary safety endpoint would be based on a peak analysis which was a separate analysis of the data done by an independent and blinded medical panel. That panel concluded that our product was not inferior to red blood cells in respect to overall medical risk. This is not the only way the agency looks at safety but it is the primary safety endpoint.

(Exhibit E at 8).

77. That statement was false, deceptive and misleading in light of the FDA's Safety Concerns and the failure by Biopure and Moore to disclose the FDA's Safety Concerns.

78. As reflected in Exhibit E hereto, at the ThinkEquity Growth Partners Conference, the Defendant Moore described in detail the history of Biopure, the status of the Hemopure BLA, the anticipated uses for and market for Hemopure, and the economics for Biopure of producing and selling Hemopure. Moore's entire presentation at that conference was false, deceptive and misleading in light of the FDA's Safety Concerns and the failure by Biopure and Moore to disclose the FDA's Safety Concerns in that presentation.

79. On September 18, 2003 Biopure issued a press release announcing that the Defendant Moore would be making a presentation at the UBS Global Life Sciences Conference on September 25, 2003. As reflected in the press release, Moore's statements at that conference were made available to the investing public. The press release, in relevant part, stated as follows:

> ...Biopure Corporation (BPUR) today announced that company President and CEO Thomas A. Moore will present at the UBS Global Life Sciences Conference on Thursday, September 25, 2003, at 12:30 p.m. EDT. The investor conference is being held at The Plaza in New York from September 22-25, 2003. A live webcast of the 25-minute presentation will be available

> online via the Investor Relations section of Biopure's web site at www.biopure.com...An archive of the webcast will be available for at least 4 days following the event.

80. On September 25, 2003, the Defendant Moore made a presentation before the UBS Global Life Sciences Conference in New York, New York. That conference was attended by securities analysts, investment advisors and other members of the investing public. Attached hereto as Exhibit F is a transcript of Moore's statements at that conference. This transcript was transcribed by Plaintiffs' counsel's personnel, from an audio tape of the Defendant Moore's presentation, which audio tape is in the possession of Plaintiffs' counsel.

81. As reflected in Exhibit F hereto, at the UBS Global Life Sciences Conference, the Defendant Moore said:

> From a safety standpoint, in our pivotal trial, we agreed before the trial began with the FDA to use as our primary safety endpoint something called a [Seep?] study. Which is basically a blinded analysis of all the case report forms by a panel of doctors who would examine each patient, create their own score of adverse events and then rank the product use again on a blinded basis in terms of how safe it was for the patient. After all the patients were rated by at least two blinded doctors, we broke the blind, and compared the accumulative scores between our products and red blood cells and achieved a safety objective which was to confirm that our product was not inferior to red blood cells with respect to overall medical risks.

(Exhibit F at 8).

82. As reflected in Exhibit F hereto, at the UBS Global Life Sciences Conference, the Defendant Moore described in detail the history of Biopure, the status of the Hemopure BLA, the anticipated uses for and market for Hemopure, and the economics for Biopure of producing and selling Hemopure. Moore's entire presentation at that conference was

false, deceptive and misleading in light of the FDA's Safety Concerns and the failure by Biopure and Moore to disclose the FDA's Safety Concerns in that presentation.

83. On October 30, 2003, before the stock markets opened, Biopure issued a press release (the "October 30 Press Release"). A copy of the October 30 Press Release is attached hereto as Exhibit G and incorporated herein by reference. The October 30 Press Release, while still not disclosing to the marketplace the FDA's Safety Concerns, disclosed some of the consequences of the FDA's Safety Concerns – particularly that the FDA would not be acting on the Hemopure BLA until sometime after June 30, 2004. This in turn had significant, negative financial implications for Biopure, some of which were outlined in the October 30 Press Release. The October 30 Press Release also disclosed that the Defendant Richman "...has left Biopure to pursue other interests."

84. The October 30 Press Release quotes the Defendant Moore as follows:

> "In the best interests of our shareholders, today we've taken the steps necessary to more efficiently run our business while we complete our comprehensive response to all of the FDA's questions," said Biopure President and CEO Thomas A. Moore. "We view the agency's questions as a 'roadmap' to approval and have set a conservative, achievable target date for our response. We remain enthusiastically committed to commercializing Hemopure in the United States as expeditiously as possible."

85. The October 30 Press Release, and Moore's above quoted statement in the October 30 Press Release, were false, deceptive and misleading in light of the FDA's Safety Concerns and the failure by Biopure and Moore to disclose the FDA's Safety Concerns.

86. The October 30 Press Release also announced that Biopure would be holding a conference call and webcast on October 30, at 11:30 am, at which "...Moore will discuss the company's regulatory and operating plans..."

87. On October 30, 2003, the Defendants Biopure, Moore and Richards participated in a telephonic conference call for analysts and institutional investors. Like the May 22 Conference Call, analysts and institutional investors could participate in the October 30 Conference Call and all members of the investing public could hear the call live and access it thereafter for a period of time. A copy of the transcript of that conference call, prepared by CCBN StreetEvents, for Biopure, is attached hereto as Exhibit H, and incorporated herein by reference. That conference call is hereinafter referred to as the "October 30 Conference Call."

88. During the October 30 Conference Call, the Defendants made statements and provided answers to questions about Biopure, the Hemopure BLA and the Trauma Clinical Trials, which were false, deceptive and misleading because they omitted and did not disclose the FDA's Safety Concerns. For example, in the October 30 Conference Call the Defendant Moore was asked about the use of Hemopure in South Africa. Moore responded as follows:

> Our stretch in South Africa has been very positive from the standpoint that we have had good experience with the patients and developed what we consider **a very good safety record** with the product.

(Exhibit H at 3, emphasis added).

89. Even though the October 30 Press Release and the Defendants' statements in the October 30 Conference Call did not disclose the FDA's Safety Concerns, they did, as observed above, disclose significant, material adverse consequences being caused to

Biopure and the Hemopure BLA, due to the FDA's Safety Concerns. The market's reaction to the disclosures in the October 30 Press Release and the October 30 Conference Call was immediate and dramatic. On October 29, 2003, the market price of Biopure stock had closed at $6.05 per share, on trading volume of 250,000 shares. October 30, 2003, the market price of Biopure stock began trading at $5.00 per share; it traded as low as $2.80 per share; and it closed at $3.68 per share on trading volume of 6,910,000 shares. Hence, the market price of Biopure stock dropped over 39% on October 30, 2003, in reaction to the October 30 Press Release and the October 30 Conference Call.

90. The extremely negative reaction to the disclosures in the October 30 Press Release and the October 30 Conference Call is also demonstrated in the October 30, 2003 article in TheStreet.com, attached hereto as Exhibit I.

91. The price of Biopure stock continued to decline after October 30. On October 31, 2003, Biopure stock closed at $3.46 per share; and on the next trading day, November 3, 2003, Biopure stock closed at $3.20 per share. Hence, in the three trading days after the October 30 Press Release and the October 30 Conference Call, the market price of Biopure declined over 47%, from its close at $6.05 per share on October 29 to its close at $3.20 per share on November 3, 2003. Thereafter the price of Biopure stock continued to decline.

92. On December 24, 2003, prior to the issuance of the December 24 Press Release (which was issued after the close of the stock market on December 24), Biopure's stock closed at $2.82 per share. December 24, 2003 is the end of the Class Period.

93. On April 30, 2004, Biopure issued a press release in which it disclosed that on April 29, 2004, the SEC staff had issued four additional Wells Notices, indicating that

the SEC staff was considering recommending that the SEC also bring civil actions against the Defendants Sanders, Crout and Rausch, and Biopure General Counsel, Jane Kober, for violations of the federal securities laws. The press release read, in part, as follows:

> CAMBRIDGE, Mass., Apr 30, 2004...Biopure Corporation (BPUR) reported today that on April 29, 2004, the U.S. Securities and Exchange Commission (SEC) issued additional "Wells Notices" to four individuals concerning matters disclosed in Biopure's press release dated December 24, 2003. The notices indicate that the SEC staff may recommend that the Commission bring a civil action against Biopure's non-executive Chairman Dr. Charles A. Sanders, former Board Member Dr. J. Richard Crout, Chief Technology Officer and Board Member Carl W. Rausch, and General Counsel Jane Kober for possible violations of federal securities laws. The notices afford the individuals an opportunity to respond in writing before the SEC staff formally decides what action, if any, to recommend.
>
> Biopure will continue to cooperate with the SEC staff in the matters investigated. As previously disclosed, Biopure believes that the SEC investigation relates to the company's disclosures concerning its communications with the U.S. Food and Drug Administration (FDA) about a proposed trauma study protocol the company submitted to the FDA in March 2003 and about the company's biologics license application (BLA) for Hemopure(R)...

THE DEFENDANTS BIOPURE AND RAUSCH SOLD MILLIONS OF DOLLARS OF BIOPURE STOCK DURING THE CLASS PERIOD, WHILE IN POSSESSION OF MATERIAL, ADVERSE, NON-PUBLIC INFORMATION REGARDING BIOPURE

94. On or about March 25, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 5,548,480 shares of Biopure common stock for $2.42 per share, for a total of $13,427,321. Those shares were registered with the SEC under a shelf registration.

95. On May 2, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 882,353 shares of Biopure common stock for $3.57 per share, for a total of $3,150,000. Those shares were registered with the SEC under a shelf registration.

96. On May 6, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 833,334 shares of Biopure common stock for $3.60 per share, for a total of $3,000,000. Those shares were registered with the SEC under a shelf registration.

97. In May and June 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 707,060 shares of Biopure common stock at an average price of $5.56 per share, for a total of $3,839,000. Those shares were registered with the SEC under a shelf registration.

98. Between August 1, 2003 and September 15, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 802,188 shares of Biopure common stock at an average price of $7.55 per share, for a total of $6,003,000. Those shares were registered with the SEC under a shelf registration.

99. In September 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 522,193 shares of Biopure common stock at a price of $4.84 per share, for a total of $2,527,000. Those shares were registered with the SEC under a shelf registration.

100. On or about July 23, 2003, while in possession of the nonpublic material adverse information regarding the Company, Biopure sold 3,083,000 shares of Biopure

common stock for $5.58 per share, for a total of $17,203,140. Those shares were registered with the SEC under a shelf registration.

101. Throughout the Class Period, while in possession of the non-public material adverse information regarding the Company, the Defendant Rausch sold a total of 276,574 shares of Biopure, for approximately $1,596,000. Those shares constituted 33.7% of the Biopure shares owned by Rausch at the beginning of the Class Period. Specifically, Rausch sold the following numbers of Biopure shares on the following dates:

DATE BIOPURE SHARES SOLD BY RAUSCH	NUMBER OF SHARES SOLD BY RAUSCH	PRICE PER SHARE	TOTAL RECEIVED BY RAUSCH
4/15/03	30,000	$3.13	$93,900
6/5/03	2,000	$6.06 - $6.07	$12,000
6/24/03	3,000	$5.58 - $5.698	$17,000
6/25/03	2,700	$5.80 - $5.97	$16,000
6/26/03	34,374	$5.80 - $5.90	$201,000
6/27/03	20,000	$5.95 - $6.00	$120,000
6/30/03	5,000	$6.14 - $6.16	$31,000
8/5/03	10,000	$7.50 - $7.53	$75,000
8/6/03	2,000	$7.50 - $7.54	$15,000
8/7/03	8,000	$7.00	$56,000
8/8/03	10,000	$7.05 - $7.28	$72,000
8/12/03	10,000	$7.00 - $7.15	$71,000
8/13/03	9,500	$7.02 - $7.15	$67,000
8/28/03	100,000	$7.50	$750,000
TOTALS	246,574		$1,596,900

102. Plaintiff Gottlieb purchased the following number of shares of Biopure common stock on the following dates:

DATE BIOPURE SHARES PURCHASED	NUMBER OF SHARES
4/17/03	3,000
4/29/03	2,500
5/19/03	2,000
5/20/03	1,400
6/23/03	1,000
8/22/03	3,000
8/25/03	1,000
8/26/03	500
TOTAL	14,400

103. Plaintiff Bittman purchased 100 shares of Biopure common stock on June 5, 2003 and 420 shares of Biopure common stock on August 26, 2003.

104. Plaintiff Esposito purchased 600 shares of Biopure common stock on August 12, 2003 and 600 shares of Biopure common stock on August 21, 2003.

SCIENTER ALLEGATIONS

105. The Defendants' conduct, as detailed herein, in issuing false, deceptive and misleading statements to the investing public about Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials was conducted by the Defendants knowingly, purposely, intentionally and recklessly, with the full knowledge that their conduct would, and with the full intention that their conduct would, mislead, deceive and act as a fraud upon the investing public.

106. In 2002, the Defendants Biopure and Rausch were named as defendants in a federal securities fraud class action entitled, *Thomas H. Meyer, et als. v. Biopure Corporation and Carl W. Rausch*, in the United States District Court for the District of Massachusetts (Civil Action No. 02-10194-EFH). In that action the Plaintiffs alleged that the Defendants had committed securities fraud by failing to disclose defects and deficiencies in the clinical trials conducted for Hemopure. Judge Harrington of this Court, in an Opinion reported at 221 F.Supp. 2d 195 (D. Mass. 2002), dismissed that complaint. In so doing, Judge Harrington, in language extraordinarily relevant to, and indeed, ironic in light of, the facts in this action, said:

> Plaintiffs also plead no basis for inferring that it is highly likely that these alleged omissions were either intentional or highly reckless...**this is not a situation where the facts omitted from the press release are so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter, since plaintiffs do not suggest that the "missing" data would show that Hemopure was unsafe**...

222 F. Supp. 2d at 207 (emphasis added).

107. Hence we see that even beyond the obvious materiality of the FDA's Safety Concerns, the Defendants knew full well, from Judge Harrington's decision in the *Meyer v. Biopure* case, that facts which "...would show that Hemopure was unsafe..." *Id.*, were not only material but "...so clearly important that the fact of non-disclosure alone gives rise to a strong inference of scienter..." *Id.* The Defendants' failure to disclose the FDA's Safety Concerns, under these circumstances, creates the strongest possible inference of *scienter*.

108. *Scienter* is also apparent here from the fact that the staff of the SEC reached the conclusion, in December 2003, based upon, *inter alia*, the facts alleged in this Complaint, that the SEC should bring proceedings against the Defendants Biopure, Moore

and Richman for violation of the federal securities laws due to their failure to disclose the FDA's Safety Concerns during the Class Period.

109. *Scienter* is also apparent here from the fact that after the SEC staff's receipt of the responses by the Defendants Biopure, Moore and Richman to the SEC staff's Wells Notices, the SEC staff responded on April 29, 2004 by issuing additional Wells Notices, advising that the SEC staff may recommend to the SEC that it also bring action against the Defendants Sanders, Rausch and Crout, as well as Biopure's general counsel, Jane Kober, for violations of the federal securities laws due to their failure to disclose the FDA's Safety Concerns during the Class Period.

110. The Defendants' *scienter* is also apparent from the highly significant and material changes which the Defendants made to the False and Deceptive Statement Regarding "*If We Fail To Obtain FDA Approval,*" after the SEC began its investigation of the Defendants during Biopure's fiscal quarter ended October 31, 2003. Specifically, in the Form S-3 registration statement filed with the SEC on August 22, 2003, which was signed by all of the Individual Defendants, except Richman, the Defendants replaced the False and Deceptive Statement Regarding "*If We Fail To Obtain FDA Approval,*" with the following statement:

> ***If We Fail to Obtain FDA Approval, We Cannot Market Hemopure in the United States***
>
> We will not be able to market Hemopure in the United States unless and until we receive FDA approval. We filed an application for approval with the FDA, and the application was accepted for review on October 1, 2002. The FDA advised us that it would complete its review and take action on the application by August 29, 2003. By letter dated July 30, 2003, the FDA gave us comments on the application, stating that it had completed its review. We are working on our responses. However, the FDA could find that our responses do not

> address its issues adequately and could require additional data or even further clinical trials ...prior to approval of Hemopure. Trials are expensive and time-consuming and we may not have the financial resources to fund such trials. Despite all of our efforts, the FDA could refuse to grant a marketing authorization.

111. Significantly, this new version of this "risk disclosure," while still deceptive and misleading because the Defendants continued to omit from it the FDA's Safety Concerns, no longer contained the Defendants' false and deceptive statement: **"We believe that our completed pivotal Phase III clinical trials are consistent with the FDA's most recent guidance on...safety endpoints required for approval of products such as Hemopure for use in surgical indications..."** which the Defendants had repeatedly falsely stated prior to August 22, 2003.

112. Another indicia of the Defendants' *scienter* is seen from the disparity between the Defendants' evasive description of the status of the Trauma Clinical Trials, and their straightforward description of the status of clinical trials of one of their potential competitors. As detailed herein, due to the FDA's Safety Concerns, the FDA placed the Trauma Clinical Trials on clinical hold in March 2003, immediately after Biopure submitted a Phase II protocol for those Trials. Thereafter, the FDA twice refused to lift that clinical hold, the last such action having occurred on May 30, 2003. Nevertheless, throughout the Class Period, the Defendants, while repeatedly discussing the Trauma Clinical Trials, fastidiously avoided disclosing the fact that the FDA had placed the Trauma Clinical Trials on a clinical hold. In contrast, at his presentation at the above described ThinkEquity Conference on September 17, 2003, when describing the research efforts of one of Biopure's potential competitors, the Defendant Moore had no hesitation in saying:

"Hemosol is now on a clinical hold. It is not clear whether it will be able to resume."

That exact same statement would have fully, accurately and non-deceptively described the status of the Hemopure Trauma Clinical Trials throughout the Class Period, and the Defendants could have, and should have, so disclosed the status of the Hemopure Trauma Clinical Trials, during the Class Period. The fact that the Defendants made this straightforward statement regarding the status of the clinical trials for their competitor's product, but did not do so regarding the Hemopure Trauma Clinical Trials, demonstrates the Defendants' *scienter* in purposely and intentionally failing to do so.

113. The Defendants' *scienter* is also seen from their extraordinary motive to deceive the investing public regarding the prospects of Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials. As the Defendants repeatedly disclosed in their SEC filings, Biopure was dependent for its continued operations and financial survival on its ability to periodically raise money from the investing public, through the sale of shares of Biopure and warrants to buy shares of Biopure. As detailed above, Biopure raised millions of dollars during the Class Period by selling its shares to investors. Biopure's ability to continue to sell its shares would have been severely compromised by the Defendants' disclosure of the FDA's Safety Concerns.

114. The Defendants' *scienter* is also seen by the sales by Biopure and Rausch of hundreds of thousands of shares of Biopure stock during the Class Period, as detailed herein.

INAPPLICABILITY OF THE SAFE HARBOR PROVISIONS OF THE EXCHANGE ACT FOR FORWARD-LOOKING STATEMENTS

115. The provisions of Section 21E of the Exchange Act, which provides, under specified circumstances, a safe harbor from liability under the Exchange Act for "forward-looking statements," are not applicable to the claims asserted herein against the Defendants.

116. Section 21E(c)(1)(B) provides that the safe harbor provisions of Section 21E do not apply if the plaintiffs prove that the forward-looking statement:

> (i) if made by a natural person, was made with actual knowledge by that person that the statement was false or misleading; or
>
> (ii) if made by a business entity; was
>
> > (I) made by or with the approval of an executive officer of that entity; and
> >
> > (II) made or approved by such officer with actual knowledge by that officer that the statement was false or misleading.

117. As demonstrated in detail herein, the Individual Defendants and Biopure had actual knowledge of the FDA's Safety Concerns throughout the Class Period. Hence, the false, misleading and deceptive statements of the Individual Defendants were made by those Individual Defendants "with actual knowledge by [those] person[s] that the statement[s were] false or misleading." Likewise, the false, misleading and deceptive statements by Biopure were "made by or with the approval of [one or more] executive officer[s] of..." Biopure, and that the executive officers of Biopure who made or approved those statements had actual knowledge "that the statement[s were] false or misleading."

118. Accordingly, the exemption provisions of Section 21E do not apply to and will not exempt the Defendants from liability for the securities fraud claims asserted against them in this action.

119. Furthermore the Defendants' statements of their opinions, projections and forecasts concerning Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials, during the Class Period, as detailed herein, were lacking in a reasonable basis at all times and did not, in fact, constitute their truly believed opinions, projections and forecasts concerning Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials, during the Class Period.

120. Furthermore, a significant number of the Defendants' false, deceptive and misleading statements, as detailed herein, were not " forward looking statements," but in fact were statements (or misstatements) of existing fact and hence the exemption provisions of Section 21E do not apply to and will not exempt the Defendants from liability for the securities fraud claims asserted against them in this action.

CLASS ACTION ALLEGATIONS

121. The Lead Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class consisting of all persons or entities who acquired shares of Biopure common stock from March 17, 2003 through December 24, 2003, (the "Class Period") and who were damaged thereby (the "Class"). Excluded from the Class are Defendants; members of the individual defendant's immediate family; any past or present director, officer, subsidiary, or affiliate of Biopure; any entity in

which any excluded person or entity has a controlling interest; and their legal representatives, heirs, successors and assigns.

122. The Plaintiffs also bring this action on behalf of a Sub-Class consisting of all persons or entities who acquired shares of Biopure common stock contemporaneously with the sales of Biopure stock by the Defendants Biopure and Rausch during the Class Period and who were damaged thereby (the "Sub-Class"). Excluded from the Sub-Class are Defendants; members of the individual defendant's immediate family; any past or present director, officer, subsidiary, or affiliate of Biopure; any entity in which any excluded person or entity has a controlling interest; and their legal representatives, heirs, successors and assigns.

123. The members of the Class and Sub-Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members of the Class and Sub-Class located throughout the United States. Throughout the Class Period, Biopure common stock was actively traded in an efficient market on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Biopure and/or its transfer agent and may be notified of the pendency of this action by mail and publication, using forms of notice similar to those customarily used in securities class actions.

124. Plaintiffs' claims are typical of the claims of other members of the Class as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

125. Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained counsel competent and experienced in class and securities litigation.

126. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

a. Whether the federal securities laws were violated by Defendants' acts and omissions as alleged herein;

b. Whether Defendants participated in and pursued the illegal course of conduct complained of herein;

c. Whether statements disseminated to the investing public during the Class Period were misrepresentations and/or suffered from omissions of material information as alleged herein;

d. Whether, when defendants Biopure and Rausch sold shares of Biopure during the Class Period, they were in possession of material, adverse, non-public information regarding Biopure, including, in particular, the FDA's Safety Concerns.

e. Whether the market price of Biopure common stock during the Class Period was artificially inflated due to the material misrepresentations and omissions complained of herein;

f. To what extent the members of the Class have sustained damages and the proper measure of damages.

g. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. As the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigations make it impossible for members of the Class individually to seek redress for the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

COUNT I

AGAINST ALL DEFENDANTS FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND RULE10b-5 PROMULGATED THEREUNDER

127. Plaintiffs repeat and reallege each and every allegation set forth above.

128. During the Class Period, Defendants, and each of them, carried out a plan, scheme and course of conduct that was intended to and/or did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; (ii) artificially inflate the market price of Biopure common stock; and (iii) cause Plaintiffs and other members of the Class to buy Biopure stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.

129. These Defendants: (a) employed devices, schemes and artifices to defraud; (b) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (c) engaged in acts, practices and a course of business which operated as a fraud and deceit upon the buyers of Biopure

common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

130. Defendants' material misrepresentations and/or omissions were done knowingly or recklessly.

131. As a result of the Defendants' dissemination of the deceptive and misleading information regarding Biopure, Hemopure, the Hemopure BLA and the Trauma Clinical Trials, and their failure to disclose the FDA's Safety Concerns regarding Hemopure, as set forth above, the market price of Biopure's common stock was artificially inflated during the Class Period. In ignorance of the fact that the market price of Biopure's shares were artificially inflated, and relying upon the integrity of the market in which Biopure common stock trades, and/or on the absence of material information that was known to and/or recklessly disregarded by Defendants but not disclosed in public statements by Defendants during the Class Period, Plaintiffs and the other members of the Class bought Biopure common stock during the Class Period at artificially inflated prices and were damaged thereby.

132. At the time of said misrepresentations and omissions, Plaintiffs and the other members of the Class were ignorant of the omitted material facts and believed Defendants' statements regarding Biopure to be completely truthful, candid and not deceptive or misleading or suffering from omissions of material facts. Had Plaintiffs and the other members of the Class known of the omitted material facts, Plaintiffs and the other members of the Class would not have bought their Biopure common stock during the Class Period, or, if they had bought such stock during the Class Period, they would not have

done so at the artificially inflated prices which they paid for their Biopure common stock which they bought during the Class Period.

133. By virtue of the foregoing, each of the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

134. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Biopure common stock during the Class Period.

COUNT II

AGAINST THE INDIVIDUAL DEFENDANTS PURSUANT TO SECTION 20(a) OF THE EXCHANGE ACT

135. Plaintiffs repeat and reallege each and every allegation set forth above.

136. This claim is asserted against the Individual Defendants pursuant to Section 20(a) of the Exchange Act, 15 U.S.C. §78t(a).

137. During the entire Class Period, the Defendants Moore, Rausch, Richards, Sanders and Crout were “controlling persons” of Defendant Biopure, within the meaning of Section 20(a) of the Exchange Act.

138. During the portion of the Class Period from March 17, 2003, to the date he resigned or was terminated as Biopure’s Senior Vice President of Regulatory Affairs and Operations, which was sometime prior to October 30, 2003, the Defendant Richman was a “controlling person” of Defendant Biopure, within the meaning of Section 20(a) of the Exchange Act.

139. The Individual Defendants were “controlling persons” of Biopure because, due to the officer and/or director positions they held with Biopure, they had the influence

and power over Biopure to cause, and they did cause, Biopure to engage in the wrongful conduct complained of herein, and because they had the power to have prevented Biopure from engaging in the unlawful conduct alleged herein, but they purposely, intentionally and recklessly did not use that power to do so.

140. As set forth above in Count I, Biopure violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by its acts and omissions as alleged in this Complaint. By virtue of their status as "controlling persons" of Biopure, the Individual Defendants are liable, to the same extent as is Biopure, for Biopure's violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, pursuant to Section 20(a) of the Exchange Act.

COUNT III

AGAINST THE DEFENDANTS BIOPURE AND RAUSCH PURSUANT TO SECTION 20A OF THE EXCHANGE ACT

141. Plaintiffs repeat and reallege each and every allegation set forth above.

142. This claim is asserted against the Defendants Biopure and Rausch pursuant to Section 20A of the Exchange Act. The Defendants Biopure and Rausch are hereinafter sometimes referred to collectively as the "Section 20A Defendants."

143. During the Class Period, the Defendants Biopure and Rausch, while in possession of the non-public material adverse information regarding the Company, sold millions of dollars of shares of the Company. Because the Section 20A Defendants possessed material adverse information about the Company which was not known to the investing public, including the members of the Sub-Class, Section 20A Defendants sold

their shares of the Company at artificially inflated prices and the members of the Sub-Class, who purchased shares of the Company contemporaneously with the sales by the Section 20A Defendants, paid artificially inflated prices for those shares of the Company, and were damaged thereby.

144. Pursuant to Section 20A of the Exchange Act, the Defendants Biopure and Rausch are liable to the members of the Sub-Class for the difference between the inflated prices at which they sold their shares of the Company during the Class Period, and the prices at which those shares would have sold had the investing public known the material adverse information about Biopure which was known to the Section 20A Defendants.

PRAYERS FOR RELIEF

WHEREFORE, Plaintiffs, on behalf of themselves and the Class, pray for judgment as follows:

A. Declaring this action to be a class action properly maintained pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure;

B. Finding that the Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by their acts and omissions as alleged in this Complaint;

C. Finding that the Defendants Biopure and Rausch violated Section 20A of the Exchange Act by their acts and omissions as alleged in this Complaint;

D. Awarding Plaintiffs and the members of the Class and the Sub-Class damages, together with interest thereon;

E. Awarding Plaintiffs and other members of the Class and the Sub-Class their costs and expenses of this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

F. Awarding Plaintiffs and other members of the Class and the Sub-Class such other and further relief as may be just and proper under the circumstances.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury.

By the attorneys for the Plaintiffs and the Class and the Sub-Class,

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